CLAIMS

What is claimed is:

1. A Zolpidem hemitartrate hydrate.

2. A Zolpidem hemitartrate monohydrate.

3. A Zolpidem hemitartrate dihydrate.

4. A Zolpidem hemitartrate trihydrate.

5. A Zolpidem hemitartrate tetrahydrate.

6. A Zolpidem hemitartrate solvate.

7. The zolpidem hemitartrate solvate of claim 6, selected from the group consisting of zolpidem hemitartrate isopropanol, zolpidem hemitartrate butanol, zolpidem hemitartrate ethylacetate and zolpidem hemitartrate acetone.

8. Zolpidem hemitartrate anhydrous.

9. Zolpidem hemitartrate with not more than 1% water content.

10. An anhydrous Zolpidem hemitartrate Form C.

11. The Zolpidem hemitartrate of claim 10, with water content of not more than 1%.

12. Zolpidem hemitartrate Form C, characterized by an X-ray powder diffraction pattern having peaks at about 7.3, 9.5, 17.8 and 23.8 ± 0.2 degrees two-theta.

13. The zolpidem hemitartrate of claim 12, further characterized by an X-ray powder diffraction pattern having peaks at about 10.7, 12.4, 13.0, 13.8, 14.6, 16.2, 18.9, 19.5, 20.3, 21.3, 23.5, 25.0, and 27.0 ± 0.2 degrees two-theta.

14. The zolpidem hemitartrate of claim 12, having particles up to about 200 microns in size, as measured by laser diffraction.

15. The zolpidem hemitartrate of claim 12, having particles up to about 50 microns in size as measured by laser diffraction.

16. A pharmaceutical composition comprising a therapeutically effective amount of the

zolpidem hemitartrate of claim 12, and a pharmaceutically acceptable carrier.

17. A method for treating a patient suffering from insomnia by administering a therapeutically effective amount of the zolpidem hemitartrate Form C.

18. Zolpidem hemitartrate Form D monohydrate.

19. Zolpidem hemitartrate Form D, characterized by a water content of about 2.3 % to about 2.7 % by weight.

20. Zolpidem hemitartrate Form D hemiethanolate.

21. Zolpidem hemitartrate Form D, characterized by an X-ray powder diffraction pattern having peaks at about 7.1, 9.5, 14.1, 19.6 and 24.5 ±0.2 degrees two-theta.

22. The zolpidem hemitartrate of claim 21, further characterized by an X-ray powder diffraction pattern having peaks at about 8.4, 10.2, 12.2, 12.9, 13.2, 15.9, 16.3, 17.7, 18.8, 21.0, 21.7, 23.0, 23.6, 25.9, 26.5, 30.0, and 30.6 ± 0.2 degrees two-theta.

23. The zolpidem hemitartrate of claim 21, having particles up to about 200 microns in size, as measured by laser diffraction.

24. The zolpidem hemitartrate of claim 21, having particles up to about 50 microns in size, as measured by laser diffraction.

25. A pharmaceutical composition comprising a therapeutically effective amount of the zolpidem hemitartrate of claim 21, and a pharmaceutically acceptable carrier.

26. A method for treating a patient suffering from insomnia by administering a therapeutically effective amount of zolpidem hemitartrate Form D.

27. Zolpidem hemitartrate Form E dihydrate.

28. Zolpidem hemitartrate Form E trihydrate.

29. Zolpidem hemitartrate Form E tetrahydrate.

30. Zolpidem hemitartrate Form E, characterized by a water content from about 5.0% to about 8.5% by weight.

31. Zolpidem hemitartrate Form E, characterized by an X-ray powder diffraction pattern having peaks at about 5.2, 7.9, 10.4, 17.2, 18.0 and 18.8 ±0.2 degrees two-theta.

32. The zolpidem hemitartrate of claim 31, further characterized by an X-ray powder diffraction pattern having peaks at about 6.8, 11.0, 13.7, 14.2, 15.8, 16.1, 19.7, 20.1, 22.2, 24.4, 25.2, 25.9, 28.5, 31.0, 31.8 and 32.5 ±0.2 degrees two-theta.

33. The zolpidem hemitartrate of claim 31, having particles up to about 200 microns in size, as measured by laser diffraction.

34. The zolpidem hemitartrate of claim 31, having particles up to about 50 microns in size, as measured by laser diffraction.

35. A pharmaceutical composition comprising a therapeutically effective amount of the zolpidem hemitartrate of claim 31 and a pharmaceutically acceptable carrier.

36. A method for treating a patient suffering from insomnia by administering a therapeutically effective amount of the zolpidem hemitartrate Form E.

37. Zolpidem Form F methanolate.

38. The zolpidem hemitartrate Form F, characterized by a methanol content of about 5.5% by weight.

39. Zolpidem hemitartrate Form F, characterized by an X-ray powder diffraction pattern having peaks at about 7.6 and 18.0 ± 0.2 degrees two-theta.

40. The zolpidem hemitartrate of claim 39, further characterized by an X-ray powder diffraction pattern having peaks at about 9.0, 12.2, 12.7, 15.7, 16.7, 17.3, 19.6, 21.6, 24.3, 24.7, 25.7, and 26.1 ±0.2 degrees two-theta.

41. The zolpidem hemitartrate of claim 39, having particles up to about 200 microns in size, as measured by laser diffraction.

42. The zolpidem hemitartrate of claim 39, having particles up to about 50 microns in size, as measured by laser diffraction.

43. A pharmaceutical composition comprising a therapeutically effective amount of the zolpidem hemitartrate of claim 39, and a pharmaceutically acceptable carrier.

44. A method for treating a patient suffering from insomnia by administering a therapeutically effective amount of the zolpidem hemitartrate Form F.

45. Zolpidem hemitartrate Form G solvate.

46. Zolpidem hemitartrate Form G, characterized by an X-ray powder diffraction pattern having peaks at about 6.8 ±0.2 degrees two-theta.

47. The zolpidem hemitartrate of claim 46, further characterized by an X-ray powder diffraction pattern having peaks at about 8.3, 8.7, 9.5, 12.2, 13.3, 15.0, 15.7, 17.5, 18.7, 19.5, 20.2, 21.4, 24.7, and 26.2 ±0.2 ± 0.2 degrees two-theta.

48. The zolpidem hemitartrate of claim 46, having particles up to about 200 microns in size, as measured by laser diffraction.

49. The zolpidem hemitartrate of claim 46, having particles up to about 50 microns in size, as measured by laser diffraction.

50. A pharmaceutical composition comprising a therapeutically effective amount of the zolpidem hemitartrate claim 46, and a pharmaceutically acceptable carrier.

51. A method for treating a patient suffering from insomnia by administering a therapeutically effective amount of the zolpidem hemitartrate Form G.

52. Zolpidem hemitartrate Form H, characterized by an X-ray powder diffraction pattern having peaks at about 7.7, 17.4, 18.0 and 24.3 ±0.2 degrees two-theta.

53. The zolpidem hemitartrate of claim 52, further characterized by an X-ray powder diffraction pattern having peaks at about 6.7, 7.7, 9.0, 9.5, 12.2, 13.2, 13.9, 15.7, 16.8, 19.6, 21.7, 24.7, 25.7, and 26.2 ± 0.2 degrees two-theta.

54. The zolpidem hemitartrate of claim 52, having particles up to about 200 microns in size, as measured by laser diffraction.

55. The zolpidem hemitartrate of claim 52, having particles up to about 50 microns in size, as measured by laser diffraction.

56. A pharmaceutical composition comprising a therapeutically effective amount of the zolpidem hemitartrate of claim 52, and a pharmaceutically acceptable carrier.

57. A method for treating a patient suffering from insomnia by administering a therapeutically effective amount of the zolpidem hemitartrate Form H.

58. Zolpidem hemitartrate form L dihydrate.

59. Zolpidem hemitartrate Form L, characterized by a water content of about 4.3% by weight.

60. Zolpidem hemitartrate Form L, characterized by an X-ray powder diffraction pattern having peaks at about 6.8, 9.7, 17.3, 19.6 and 21.1 ±0.2 degrees two-theta.

61. The zolpidem hemitartrate of claim 60, further characterized by an X-ray powder diffraction pattern having peaks at about 7.5, 10.6, 13.2, 13.9, 16.4, 17.7, 21.6, 23.2, 23.6, 26.3, 27.1 and 29.7 ± 0.2 degrees two-theta.

62. The zolpidem hemitartrate of claim 60, having particles up to about 200 microns in size, as measured by laser diffraction.

63. The zolpidem hemitartrate of claim 60, having particles up to about 50 microns in size, as measured by laser diffraction.

64. A pharmaceutical composition comprising a therapeutically effective amount of the zolpidem hemitartrate of claim 60, and a pharmaceutically acceptable carrier.

65. A method for treating a patient suffering from insomnia by administering a therapeutically effective amount of the zolpidem hemitartrate Form L.

66. A method for synthesizing zolpidem hemitartrate, comprising the steps of:

(a) forming a zolpidic acid halide from the zolpidic acid;

(b) reacting zolpidem acid halide, with dimethyl amine, to form zolpidem base;

(c) forming zolpidem hemitartrate salt from the zolpidem base.

67. The method of claim 66, wherein the step of forming a zolpidic acid halide further comprises using DMF as a co-solvent for the reaction to facilitate the contact of thionylchloride and zolpidic acid.

68. The method of claim 66, further comprising using toluene as a crystallization solvent to purifies effectively zolpidem.

69. The method of claim 66, further comprising using DMF as co-solvent to improve the purification effect of Zolpidem.

70. The method of claim 66, further comprising using toluene as a transport medium for the effective removal of the excess of thionylchloride from the reaction mass.

71. The method of claim 66, wherein the step of forming a zolpidic acid halide further comprises, using toluene as a reaction medium in which the acid chloride precipitates avoiding the undesired additional chlorination reaction of zolpidic acid.

72. The method of claim 66, wherein the step of forming a zolpidic acid halide further comprises, using toluene as a crystallization solvent for zolpidem and acid chloride.

73. The method of claim 66, wherein the step of forming a zolpidic acid halide further comprises, using toluene as a reaction medium for "one pot" reaction from zolpidic acid to zolpidem.

74. The method of claim 66, wherein the halide is chloride.

75. The method of claim 74, wherein the step of forming the acid chloride is performed using thionyl chloride.

76. The method of claim 74, wherein the step of forming the acid halide is performed

using toluene as a solvent.

77. The of method of claim 66, further comprising the step of forming a crystal form of zolpidem hemitartrate.

78. The method of claim 66, further comprising the step of crystallizing the zolpidem hemitartrate Form A from the solution.

79. The method of claim 66, further comprising the step of heating zolpidem hemitartrate to a temperature from about 70°C to about 150°C to form zolpidem hemitartrate Form C.

80. The process of claim 79, wherein the zolpidem hemitartrate is a form selected from the group of zolpidem hemitartrate polymorphs consisting of Forms A, D, E, F, and G, H, L.

81. The of method of claim 66, further comprising the step of exposing zolpidem hemitartrate to vapors of ethanol to form zolpidem hemitartrate Form D.

82. The process of claim 81, wherein the zolpidem hemitartrate is a crystal form of zolpidem hemitartrate, selected from the group of crystal forms of zolpidem hemitartrate consisting of Form A and Form C.

83. The of method of claim 66, further comprising the step of exposing zolpidem hemitartrate to water vapor at a relative humidity of about 100% to form zolpidem hemitartrate Form E.

84. The method of claim 83, wherein the zolpidem hemitartrate is a crystal form of zolpidem hemitartrate selected from the group of crystal forms of zolpidem hemitartrate consisting of Form A, Form C and Form D.

85. The method of claim 66, further comprising the step of exposing zolpidem hemitartrate to vapors of methanol to form zolpidem hemitartrate Form F.

86. The method of claim 85, wherein the zolpidem hemitartrate is a crystal form of

zolpidem hemitartrate selected from the group of a crystal forms of zolpidem hemitartrate consisting of Form A and Form C.

87. The method of claim 66, further comprising the step of exposing zolpidem hemitartrate Form A to vapors of ethyl acetate to form zolpidem hemitartrate Form G.

88. The method of claim 66, further comprising the step of slurrying zolpidem hemitartrate Form A in ethanol to form zolpidem hemitartrate Form H.

89. The method of claim 66, further comprising:

(a) dissolving zolpidem hemitartrate in a solvent mixture of methanol and water;

(b) precipitating zolpidem hemitartrate from the solvent mixture; and,

(c) isolating zolpidem hemitartrate,

to form zolpidem hemitartrate Form L.

90. A process for preparing zolpidem hemitartrate Form C, comprising the steps of exposing zolpidem hemitartrate Form A to vapors of isopropyl alcohol.

91. A process for preparing zolpidem hemitartrate Form C, comprising the step of heating zolpidem hemitartrate to a temperature from about 70°C to about 150°C for a sufficient time to convert zolpidem hemitartrate to Form C .

92. A process for preparing zolpidem hemitartrate Form D, comprising the step of exposing zolpidem hemitartrate Form A to water vapor at a relative humidity from about 60% to about 100%.

93. A process for preparing zolpidem hemitartrate Form D, comprising the step of exposing Form C to water vapor at a relative humidity of about 100%.

94. A process for preparing zolpidem hemitartrate Form D, comprising the step of exposing zolpidem hemitartrate Form A to vapors of ethanol.

95. A process for preparing zolpidem hemitartrate Form D, comprising the step of

exposing zolpidem hemitartrate Form C to vapors of ethanol.

96. A process for preparing zolpidem hemitartrate Form D, comprising the step of forming a slurry of zolpidem hemitartrate Form A in ethylacetate.

97. A process for preparing zolpidem hemitartrate Form D, comprising the step of forming a slurry of zolpidem hemitartrate Form A in acetone.

98. A process for preparing zolpidem hemitartrate Form D, comprising the step of granulating zolpidem hemitartrate Form A in isopropanol.

99. A process for preparing zolpidem hemitartrate Form C, comprising the step of forming a slurry of zolpidem hemitartrate Form A in isopropanol.

100. A process for preparing zolpidem hemitartrate Form D, comprising the step of granulating zolpidem hemitartrate Form A in butanol.

101. A process for preparing zolpidem hemitartrate Form E, comprising the step of exposing a solid form of zolpidem hemitartrate to water vapor at a relative humidity of about 100%.

102. A process for preparing zolpidem hemitartrate Form E, comprising the step of forming a slurry of a solid form of zolpidem hemitartrate in water.

103. A process for preparing zolpidem hemitartrate Form E, comprising the step of granulating a solid form of zolpidem hemitartrate in water.

104. A process for preparing zolpidem hemitartrate Form F, comprising the step of exposing a solid form of zolpidem hemitartrate to vapors of methanol.

105. A process for preparing zolpidem hemitartrate Form G, comprising the step of exposing zolpidem hemitartrate Form A to vapors of ethyl acetate.

106. A process for preparing zolpidem hemitartrate Form G, comprising the step of forming a slurry of zolpidem hemitartrate Form C in ethanol.

107. A process for preparing zolpidem hemitartrate Form G, comprising the step of

forming a slurry of zolpidem hemitartrate Form C in methanol.

108. A process for preparing zolpidem hemitartrate Form G, comprising the step of granulating zolpidem hemitartrate Form C in ethanol.

109. A process for preparing zolpidem hemitartrate Form G, comprising the step of granulating zolpidem hemitartrate Form C in methanol.

110. A process for preparing zolpidem hemitartrate Form H, comprising the step of slurrying zolpidem hemitartrate Form A in ethanol.

111. A process for preparing zolpidem hemitartrate Form H, comprising the step of slurrying zolpidem hemitartrate Form A in methanol.

112. A process for preparing zolpidem hemitartrate Form H, comprising the step of granulating zolpidem hemitartrate Form A in ethanol.

113. A process for preparing zolpidem hemitartrate Form H, comprising the step of granulating zolpidem hemitartrate Form A in methanol.

114. A process for preparing zolpidem hemitartrate Form L, comprising the step of:

(a) dissolving zolpidem hemitartrate in a solvent mixture of methanol and water;

(b) precipitating zolpidem hemitartrate from the solvent mixture; and,

(c) isolating zolpidem hemitartrate.

115. The process of claim 114, wherein the solvent mixture of methanol and water is at a ratio of about 13 parts methanol to about 1 part water.

116. Zolpidem hemitartrate having particles up to about 200 microns in size.

117. Zolpidem hemitartrate having particles up to about 50 microns in size.

118. A pharmaceutical composition comprising a therapeutically effective amount of zolpidem hemitartrate particles up to about 200 microns in size as measured by laser diffraction and, a pharmaceutically acceptable carrier.

119. The pharmaceutical composition of claim 118, wherein the zolpidem hemitartrate particles are selected from the group consisting of Form A, Form B, Form C, Form D, Form E, Form F, Form G, Form H and Form L.

120. A pharmaceutical composition comprising a therapeutically effective amount of zolpidem hemitartrate particles up to about 50 microns in size as measured by laser diffraction and, a pharmaceutically acceptable carrier.

121. The pharmaceutical composition of claim 120, wherein the zolpidem hemitartrate particles are selected from the group consisting of Form A, Form B, Form C, Form D, Form E, Form F, Form G, Form H and Form L.

122. Micronized zolpidem hemitartrate Form A having particles up to about 200 microns in size as measured by laser diffraction and an x-ray diffraction pattern having a peak at about 8.6 ±0.2 degrees two-theta.

123. The zolpidem hemitartrate of claim 122, further characterized by an x-ray diffraction pattern having peaks 6.7, 11.2, 15.4 and 17.3 ±0.2 degrees two-theta.